UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CITY OF LIVONIA EMPLOYEES' RETIREMENT SYSTEM, On Behalf of Itself and All Others Similarly Situated,	:	
Plaintiffs,	:	Civil Action No. 07 CV 10329 (RJS)
vs.	:	
WYETH, ROBERT ESSNER, JOSEPH MAHADY, KENNETH MARTIN, BERNARD POUSSOT, ROBERT RUFFOLO, JR. and GINGER CONSTANTINE,	:	
Defendants.	:	

REPLY MEMORANDUM OF LAW IN SUPPORT OF ALL DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT

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PRELIMINARY STATEMENT

In their opening brief, Defendants demonstrated that the Complaint must be dismissed because it does not plead – as it must – a false or misleading statement, loss causation, or scienter. Recognizing this, Plaintiffs respond with several deficient devices in the hope that the Court will accept at least one of them to salvage the Complaint. Primarily, Plaintiffs refocus the theory of the case, now saying that it is not about false and misleading statements concerning FDA approval, but is about the failure to disclose negative data from one particular drug trial out of several.[1] In refocusing their theory, Plaintiffs argue fraud by hindsight, claiming that because something negative happened (FDA approval not coming when hoped for), Defendants must have known material information and lied about it. Relying on the fraud by hindsight argument, Plaintiffs proffer a duty to disclose study data based on an erroneous claim of statistical significance that misconstrues the appropriate legal standard. Finally, Plaintiffs strenuously argue conclusory statements in place of facts, hoping the difference will go unnoticed.

This remains a case in which Plaintiffs allege that Defendants knowingly or recklessly made misleading statements about the prospects for FDA approval of a drug. Indeed, FDA approval is expressly referenced in the Complaint *over twenty times*. Cases like this are brought and dismissed regularly, and this case is no different.[2]

In an effort to refocus their case, Plaintiffs argue that the Company committed a securities fraud by failing to disclose adverse event data about Pristiq from Study 315. Plaintiffs misstate the law and facts. Contrary to Plaintiffs' attempt to impose a "disclosure based on hindsight" obligation on Defendants, the Second Circuit requires disclosure of adverse data only

[1] All abbreviations used herein are defined as in the Memorandum of Law in Support of All Defendants' Motion to Dismiss the Consolidated Complaint ("Motion").

[2] *See In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453 (S.D.N.Y. 2008); *In re Connetics Corp. Sec. Litig.*, 542 F. Supp. 2d 996 (N.D. Cal. 2008); *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. 04 Civ. 1030, 2005 WL 4161977 (D. Colo. Oct. 20, 2005); *In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 557 (S.D.N.Y. 2004).

where there is statistically significant evidence that the ill effects may be **caused by** use of the drug. *See In re Carter-Wallace, Inc. Sec. Litig.* (*Carter-Wallace II*), 220 F.3d 36, 40-41 (2d Cir. 1998). Here, the Study 315 Report shows that the cardiac, hepatic and hypertension results that Plaintiffs claim were not disclosed were not statistically significant, and the Study does not reach the conclusion that these statistically insignificant events may be caused by use of the drug. Moreover, Wyeth had a larger universe of data on Pristiq from other trials that were not showing evidence of a causal link between Pristiq and adverse cardiac and hepatic events. Accordingly, Wyeth had no duty to disclose the Study 315 data that Plaintiffs complain about.

It is an unusual securities case where Defendants publicly disclose alleged omissions to the financial and medical communities. Despite having no duty to disclose, Wyeth *did* disclose the cardiac data from Study 315 during the Class Period and it did not cause the stock price to drop. Wyeth reported the hypertension outcome in the very October 2006 analyst presentation to which Plaintiffs cite. Wyeth reported the cardiac along with the hypertension data at the May 2007 conference of the American College of Obstetricians and Gynecologists. This information was subsequently analyzed and reported on by a Prudential analyst, who predicted that it would not negatively impact FDA approval. As a matter of law, there can be no omission where the allegedly "hidden" information has been placed in the public domain. Significantly, the share price did not drop in reaction to this data. Rather, the price dropped in July 2007 after Wyeth reported on the FDA's "approvable" letter.

Plaintiffs argue that the share price dropped in July 2007 due solely to disclosure of the safety data, but this ignores both the prior disclosure of the cardiac data and the fact of the FDA action. Courts will not endorse such a selective interpretation of the record. In *In re*

Pfizer, Inc. Securities Litigation, a recent dismissal in this Court, defendants announced that their clinical drug trials would be halted, causing a decline in stock price, and the court stated:

> [P]laintiffs argue that the sudden drop in stock price after the "revelation of previously undisclosed information" prevents a conclusion that the allegedly omitted information was absorbed by the market. This is not persuasive. The drop in stock price did not follow the revelation of the allegedly omitted fact—that there was conflicting evidence about [the drug's] efficacy. Rather . . . it followed the "sudden news . . . that the clinical trials were being halted," **a development that was significant independent of whether there previously had been conflicting evidence of [the drug's] efficacy**.

538 F. Supp. 2d 621, 633 (S.D.N.Y. 2008) (emphasis added). Similarly, the FDA approvable letter was a development that was significant independent of the information in the marketplace regarding the outcomes of Pristiq's clinical trials. That is what affected the product's revenue-generating ability, and that is what Defendants were unable to predict, which is not actionable.

Finally, Plaintiffs' theory of scienter is implausible and fails under *Tellabs* because it is less compelling than Defendants' practical explanation for their behavior. As a matter of law, courts will disregard generic allegations that corporate executives were motivated to tout their products' successes, replace old drugs, or keep up their stock price. Here, Plaintiffs' allegedly more specific story is completely implausible. Plaintiffs acknowledge that Defendants disclosed the cardiac data from Study 315 but claim they hid the hepatic data. It makes no sense for executives trying to deceive the market about a product's safety to disclose the outcomes that are clearly more significant (heart attacks and coronary occlusions) and the outcome that Plaintiffs claim is the "most startling" (hypertension) and yet hide others. Rather, the record shows that Defendants did not believe the Study 315 outcomes that Plaintiffs complain about would prevent Pristiq's approval; they openly disclosed them to the FDA; and they disclosed the safety data to doctors at the ACOG conference who might have a greater interest in them.

Plaintiffs' allegations regarding stock sales fare no better, as the sales were not suspiciously timed, were not unusual in size or nature, and are easily explained by the opening of the closed trading window in October 2006, and in the case of Mr. Martin, by his resignation in the spring of 2007. Ultimately, Plaintiffs fail to come to terms with the fact that the senior executives' interests were aligned with long-term growth based on their holdings in long-term restricted stock and their receipt of stock options in April 2007, and not a short-term spike that would drop once the FDA's regulatory action was announced. Again, Plaintiffs' theory of the case is internally inconsistent and does not survive a *Tellabs* inquiry.

For all of these reasons, Plaintiffs' Complaint fails to allege a case of fraud. Indeed, Plaintiffs have done no more than recount a factual story of one pharmaceutical company that hoped for FDA approval of a new drug but found itself subject to a tighter approval process than could have been historically anticipated.[3] Because no amount of repleading will cure the Complaint's deficiencies, this securities case should be dismissed with prejudice.

ARGUMENT

I. PLAINTIFFS HAVE NOT ALLEGED ACTIONABLE STATEMENTS OR OMISSIONS

A. Defendants' Alleged Misstatements Are Either Protected As Forward-Looking or Otherwise Non-Actionable

1. Defendants' Statements Regarding FDA Approval Are Forward-Looking

Plaintiffs argue that Defendants' statements "were not forward looking." Mem. of Law in Opp'n to Motion ("Opp'n") at 20. Yet the Complaint is replete with statements attributed to Defendants about the likelihood of FDA approval of Pristiq for VMS *in the future*:

[3] As a spokesperson for the FDA stated in November 2007, "**I would not be surprised if the decisions we make now are different from decisions we would make in the past when looking at the same set of data.**" Chepiga Decl. Ex. 1 (emphasis added); *see also id.* Ex. 2 ("After years of public ridicule and congressional scrutiny, the [FDA] is taking a tougher stance against drugmakers in its review of new medicines."); *id.* Ex. 1 ("The explanation most often heard for the spike in approvable letters is the obvious one: that FDA has raised the bar for drug safety."); *id.* Ex. 3 (describing congressional pressure on FDA to increase regulatory scrutiny).

- § "we think we have a package that could warrant **approvability by FDA**";
- § "I think it's fair to say that our regulatory and clinical teams, however, remain pretty optimistic that the current filing can result in **favorable action** by April 23rd";
- § "[w]e think the package that we filed is an **approvable** one"; and
- § "[w]e're **optimistic about approval** . . . [f]ollowing FDA approval we'll be prepared to launch Pristiq in the U.S."

Compl. ¶ 36 (emphasis added). Plaintiffs' Opposition also argues that Defendants predicted that Pristiq "*would* benefit millions of women;" "*would* generate billions of dollars in revenue;" and "*would* fill a significant unmet medical need in women's health." Opp'n at 13 (emphasis added). All of these statements fall within the PSLRA's definition of forward-looking and the safe harbor provided by the "bespeaks caution" doctrine. *See* 15 U.S.C. § 78u-5(i)(1) (2008); Mot. at 13.

2. Defendants' Statements Were Accompanied by Meaningful Cautionary Language

Plaintiffs also incorrectly assert that the warnings accompanying Defendants' forward-looking statements are insufficient. *See* Opp'n at 22. A pharmaceutical company is shielded from liability for projections about FDA approval where it warns investors that it is not making any guarantees. *See* Mot. at 13-17. That is precisely what Wyeth did:

> [C]linical trial data are subject to differing interpretations and, even when we view the data as sufficient to support the safety and/or effectiveness of a product candidate or a new indication for an existing product, **regulatory authorities may not share our views and may require additional data** or may deny approval altogether.

See Mot. at 2-3 (emphasis added). Given these warnings to investors not to rely on a specific FDA outcome, Defendants' forward-looking statements regarding hoped-for FDA approval are not actionable, as other courts have regularly concluded in similar circumstances.[4]

[4] *See AstraZeneca*, 559 F.Supp. 2d 453, 471; *Connetics*, 542 F.Supp. 2d 996, 1006-08; *Noble*, 2005 WL 4161977, at *8-10; *Bristol-Myers*, 312 F. Supp. 2d 549, 557-59.

3. The Complaint Does Not Allege That Defendants Knew That the FDA Would Not Issue an Approval Letter

Plaintiffs argue that "Defendants knew that their statements were false and misleading when made," Opp'n at 23, but offer no supporting facts. As shown, Defendants' forward-looking statements pertain to the hoped-for FDA approval of Pristiq for VMS. Thus, Plaintiffs' emphasis on Defendants' knowledge of the Study 315 safety data is misplaced. Here, the Complaint has no factual allegations demonstrating that Defendants knew the FDA would delay approval of Pristiq. The May 21, 2007 Prudential analyst report further supports the reasonableness of Defendants' optimism, as the analyst similarly concluded that FDA approval of Pristiq for VMS was likely. *See* Mot. at 19; *Miss. Pub. Employees Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75, 90 (1st Cir. 2008) ("[A] plaintiff may not simply contrast a defendant's past optimism with less favorable actual results, and then 'contend that the difference must be attributable to fraud.'"). As such, Defendants' statements are protected from liability under the PSLRA's safe harbor provision and the "bespeaks" caution doctrine.

4. Plaintiffs' Allegations Fail Regarding Defendants' Statements About Pristiq's "Safety"

Finally, Plaintiffs argue that Defendants' statements that were not forward-looking – those regarding the safety of Pristiq – were false and misleading. *See* Opp'n at 13-14. For example, Plaintiffs state that Defendants assured investors that Pristiq was "safe and effective" and was "[s]imilar to Effexor XR in terms of its efficacy, safety, and tolerability." *Id.* at 13; Compl. ¶ 69. As an initial matter, Plaintiffs misrepresent the latter statement, as it was not in reference to the use of Pristiq to treat VMS, but rather with respect to the use of Pristiq to treat MDD, for which the drug received FDA approval. *See* Chepiga Decl. Ex. 4. Moreover, to the

extent factual information is contained within the statement, these facts are true.[5] Plaintiffs fail to allege why Pristiq is not similar to Effexor, as they do not present any information relating to Effexor at all. Finally, these statements reflect Wyeth's value-based judgment and opinion that Pristiq is safe and effective. As a result, these statements are not actionable. *See, e.g., Bristol-Myers*, 312 F. Supp. 2d at 557 ("[S]tatements of opinion are insufficient to form the basis of a misrepresentation or omission complaint under § 10(b).").

B. Plaintiffs Have Misconstrued the Securities Cases on Pharmaceutical Companies' Duty to Disclose Adverse Events

1. Defendants Had No Duty to Disclose the Study 315 Results

Plaintiffs argue that Defendants had a duty to disclose the results of Study 315 because "the adverse data . . . was statistically significant" and "threatened the commercial viability of Pristiq for VMS." *See* Opp'n at 15-16. Plaintiffs misconstrue the relevant facts and the governing legal standard.

As a factual matter, the cardiac, hepatic and hypertension outcomes that Plaintiffs cite are not statistically significant. As set forth in the Study 315 Report, the statistical values attached to these outcomes do not reach the level of statistical significance. *See* Chepiga Decl. Ex. 5 at 395, 397-399, 885, 910, 939 (showing that p values for cardiac, hepatic and hypertension events were greater than 0.05). Plaintiffs' calculation of statistical significance by citing the increased percentage of an incident occurring in the overall treatment group compared to the placebo group is simply an erroneous statistical analysis. [6] *See, e.g.*, Opp'n at 16. Moreover, this approach does not account for the 8 to 1 randomization of subjects into treatment groups versus

[5] Defendants present a numerical comparison of Effexor XR and Pristiq for MDD, for both efficacy and adverse events, in their October 5, 2006 presentation cited in the Complaint. *See* Chepiga Decl. Ex. 4.

[6] Plaintiffs' assertion that the Study 315 results are "statistically significant" is based on an erroneous one-to-one comparison to the placebo group. *See, e.g.*, Opp'n at 6 (claiming that results of Study 315 were statistically significant because patients in test group "were 353% to 508% more likely to suffer hypertension"). Determining statistical significance involves a sophisticated statistical analysis of the data in relation to a multitude of factors, including the large disparity between the population sizes of the experimental and placebo groups.

placebo; in other words, there were 8 times as many subjects in the 707 person study receiving Pristiq as receiving the placebo. A straight count of adverse incidents in all the treatment groups compared to placebo therefore overstates the issues. For example, looking solely at the 100 mg dose group for which Wyeth sought FDA approval for VMS, only **one** patient had a serious cardiac disorder (a coronary artery occlusion), which study investigators concluded was "probably not" related to the drug, and only **one** patient had a serious hepatic disorder, which study investigators concluded was "definitely not" related to the drug.[7] Based on these facts, all available in the Study 315 Report, Plaintiffs' arguments that these results were "statistically significant," "material," and known in advance to threaten the drug's commerciability cannot stand.

As a legal matter, Plaintiffs overstate pharmaceutical companies' obligation to disclose serious adverse events. The Second Circuit has held that drug companies are required to disclose adverse study results only if the data "provide **statistically significant evidence** that the ill effects may be **caused by—rather than randomly associated with**—use of the drugs." *In re Carter-Wallace, Inc. Sec. Litig.* (*Carter-Wallace I*), 150 F.3d 153, 157 (2d Cir. 1998); *see also Carter-Wallace II*, 220 F.3d at 38-39. In *Carter-Wallace II*, the Second Circuit dismissed plaintiffs' claims, explaining that an adverse event "does not in and of itself show a **causal relationship** between [the drug] and the illness." 220 F.3d at 41 (emphasis added).

[7] This Court may review the Study 315 Report because Plaintiffs rely on its data and results in their Complaint. *See ATSI Commc'ns, Inc. v. Shaar Fund Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007). The Report does not draw conclusions about a causal link between Pristiq and the limited serious adverse incidents. As the Report states, of the 629 total subjects in the treatment groups, only "3 subjects had events considered by the investigators to be possibly or probably related to test article. . . . **All other serious adverse events were considered to be either definitely or probably not related to test article.**" Chepiga Decl. Ex. 5 at 76-77 (emphasis added). The three "possibly related" events did not occur in the dosage group submitted for approval for VMS (100 mg); were hepatic; and were not statistically significant. *See id.* Ex. 5 at 32-33, 76-77, 885, 910, 939.

Other courts have also routinely dismissed cases where, as here, Plaintiffs have not alleged facts regarding a "causal relationship" between the drug and the adverse outcome. *See N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, No. 07-2626, 2008 WL 3115355, at *11-15 (1st Cir. Aug. 7, 2008) (granting motion to dismiss because, *inter alia*, the complaint failed to allege a "*causal relationship*" between the drug and the reported infections) (emphasis added); *In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 214 (S.D.N.Y. 2008) (granting motion to dismiss because "Plaintiffs do not allege facts that . . . support an inference that a *causal relationship* between [the drug and the adverse events] was established") (emphasis added); *In re Intrabiotics Pharm., Inc. Sec. Litig.*, No. 04-02675, 2006 WL 708594, at *11 (N.D. Cal. Jan. 23, 2006) (granting motion to dismiss because plaintiffs did not allege at what point it became apparent that the drug was "*causing* adverse results") (emphasis added); *In re Alliance Pharm. Corp. Sec. Litig.*, 279 F. Supp. 2d 171, 189 (S.D.N.Y. 2003) ("The Second Circuit . . . recognize[s] that not every adverse effect in a clinical trial is automatically material, and that *causation*, as well as statistical significance, is key.") (emphasis added).

Here, Plaintiffs' Complaint fails from the same infirmities and should be dismissed. Plaintiffs have not alleged *facts* to demonstrate that Study 315 provides "statistically significant evidence that the ill effects may be caused by" Pristiq. As the Study 315 Report shows, the adverse data to which Plaintiffs cite were *not* statistically significant. And, the study investigators found that the two serious cardiac and hepatic events in the relevant dosage group were "definitely not" or "probably not" related to the drug. Moreover, when a drug company assesses the relationship between a drug and potential side effects, it looks at the entire universe of data available at the time. In the case of Pristiq, the universe of data from multiple studies involving VMS, MDD, fibromyalgia, and neuropathic pain has not shown "statistically

significant evidence" that a causal link may exist between the drug and serious adverse cardiac and hepatic events, as evidenced by Wyeth's planned 2008 FDA submissions for neuropathic pain and fibromyalgia. *See id.* Ex. 4. Plaintiffs themselves do not point to any other data, and specifically state that they are not relying on Studies 319 and 321. *See* Opp'n at 25 n.11. Significantly, the FDA approved Pristiq in the MDD context and had access to the same universe of data regarding Pristiq's safety profile.

Given all of the factors that the Court is allowed to consider on a motion to dismiss, Plaintiffs have failed to show that Wyeth had any duty to disclose the safety data they complain about. Plaintiffs' argument that Defendants should nonetheless have anticipated that the FDA, in a new era of heightened regulatory scrutiny, would require additional safety data before giving approval for the VMS indication is nothing more than an argument of fraud by hindsight, a theory rejected by the courts. *See Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129 (2d Cir. 1994) ("We have rejected the legitimacy of 'alleging fraud by hindsight.'").

2. Defendants Nevertheless Disclosed Safety Data From Study 315 During the Class Period

Defendants have demonstrated that, although they were not required to, they did disclose the Study 315 cardiovascular data in May 2007 at the ACOG conference, which was then reported to the public in a May 21, 2007 analyst report.[8] *See* Mot. at 18-19. With respect to the cardiac events, the ACOG disclosure stated that "[d]ue to multiple underlying cardiac risk factors in the subjects who experienced cardiovascular events, the lack of dose-clustering, and because those events were rare, no dose or **causal relationship** could be ascertained." Mot. Aff.

[8] Plaintiffs claim "high blood pressure" was not disclosed. *See* Opp'n at 25. However, hypertension is disclosed on the Poster presented at the ACOG conference in "adverse events" under "Cardiovascular" and is included in the analyst report. Mot. Aff. Exs. 11, 12.

Ex. 11 (emphasis added). With respect to hypertension, Wyeth disclosed that outcome in the October 2006 analysts presentation and at the ACOG conference. *See* Chepiga Decl. Ex. 4.

Realizing the significance of this disclosure, Plaintiffs initially respond by asking the Court to disregard the ACOG poster and analyst report. *See* Opp'n at 24 n.10. The poster, however, is incorporated by reference into the Complaint, which quotes from a May 9, 2007 Wyeth press release discussing "[t]he *data… presented* at the 55th Annual Meeting of the [ACOG]." Compl. ¶ 100 (emphasis added). The analyst report is not being offered for the truth of the information contained therein, but instead to establish that certain information was disseminated to the market at a certain point in time.[9] *See In re Amgen Sec. Litig.*, 544 F. Supp. 2d 1009, 1023-24 (C.D. Cal. 2008) ("Among the public documents a court may consider on a motion to dismiss securities fraud claims are analyst reports when they are submitted to establish 'whether and when certain information was provided to the market.'").

Plaintiffs next argue that these disclosures were insufficient because "[e]ven complete warnings, when accompanied by counterbalancing reassurances will not establish a truth-on-the-market defense." Opp'n at 25. First, the *Pfizer* court states that "the relevant inquiry is not whether the truth was absorbed by the market, but whether it was available to the market." *Pfizer*, 538 F. Supp. 2d. at 632. Second, neither of the cases to which Plaintiffs cite— *Freedland v. Iridium World Communications, Ltd.* and *Ganino v. Citizens Utilities*— articulates the principle for which Plaintiffs cite it. In fact, a district court, relying on *Ganino*, granted a motion to dismiss on the ground that "the information plaintiffs claim was concealed by defendants was publicly available . . . and on these facts the law renders defendants' purported misstatements immaterial." *White v. H&R Block, Inc.*, No. 02 Civ. 2289, 2004 U.S. Dist. LEXIS

[9] Plaintiffs contend *In re Zyprexa Products Liability Litigation* is "unpersuasive" because it is a summary judgment decision, but the court stated: "In deciding a motion to dismiss or summary judgment . . . [j]udicial notice can be taken of . . . analyst reports in determining what the market knew." 549 F. Supp. 2d 496, 500-01 (E.D.N.Y. 2008).

14522, at *36 (S.D.N.Y. July 28, 2004). Similarly, in *Pfizer*, the court found that allegedly omitted facts about a drug's efficacy were immaterial, just as they are here, because **analysts' reports had discussed them**. 538 F. Supp. 2d 621, 632-33 (S.D.N.Y. 2008).

Finally, Plaintiffs argue that the disclosures were incomplete because they did not reference the hepatic events. Plaintiffs' argument does not make sense. If Defendants were truly trying to hide adverse information, they would not disclose the more serious events and hide others. The Complaint itself identifies the cardiac events as more significant ("heart attacks, partial or complete obstruction of the coronary artery, and hypertension") and expressly alleges that "[p]erhaps the most startling adverse event[] . . . was that of increased high blood pressure." Compl. ¶ 25. Moreover, when the events that Plaintiffs allege to be more serious were disclosed, they had no effect on the share price. Here, Defendants disclosed the cardiovascular data in May 2007 and there was **no meaningful change** in the stock price. *See* Mot. at 20. It makes no sense to claim that less significant safety data were being purposely withheld or would have had a different effect on the share price. Defendants' alleged "omissions" are thus immaterial and therefore not actionable.

II. PLAINTIFFS HAVE NOT ALLEGED LOSS CAUSATION

Plaintiffs mistakenly argue that the Complaint alleges loss causation because the July 24, 2007 press release regarding FDA approval also referred to the Study 315 data, and Wyeth's stock price fell the following day. Opp'n at 38. Plaintiffs are trying to resist dealing with the unavoidable fact that the market knew about cardiovascular events of Study 315 in May 2007, and this knowledge did not cause a drop in the price of the Company's stock.

In *Pfizer*, plaintiffs alleged that defendants had omitted material information about the efficacy of a new drug when touting its benefits during clinical trials. 538 F. Supp. 2d at 626. Defendants later announced that they were stopping all trials, and the price of the

company stock fell. *Id.* The court noted that "the allegedly omitted information was available to the market [prior to the Company's announcement] because . . . analysts' reports acknowledged the conflicting evidence of [the drug's] efficacy." *Id.* at 633. The court found the announcement of the clinical trials' termination to be significant independent of the alleged omission. *See id.* The court's finding in *Pfizer* upholds the standard that an allegation of loss causation fails "[u]nless [the plaintiff] can establish that his losses were attributable to some form of revelation to the market of the wrongfully concealed information." *In re Worldcom, Inc. Sec. Litig.*, 02 Civ. 3288, 2005 WL 2319118, at *23 (S.D.N.Y. Sept. 21, 2005).

Similarly, the cardiovascular and hypertension results were disclosed to the market in May 2007 with no decline in the price of Company stock. The relevant "new" information disclosed in July 2007 was the FDA's issuance of an approvable letter. As in *Pfizer*, the market was aware of adverse events that had occurred in the Pristiq study and was able to factor that information into its assessment of the Company's stock. As a matter of law, Plaintiffs' claim fails on loss causation because the disclosed fact must be new to the market.

III. PLAINTIFFS HAVE NOT SUFFICIENTLY ALLEGED SCIENTER

A. Plaintiffs Have Not Alleged Motive and Opportunity

1. Plaintiffs' Theory of the Case Is Incoherent

In order for an alleged motive to be sufficient, it must be coherent, as "allegations of irrational motive cannot support a fraud claim." *Hampshire Equity Partners II, L.P. v. Teradyne, Inc.*, No. 04 Civ. 3318, 2005 WL 736217, at *3 (S.D.N.Y. Mar. 30, 2005). In addition, a complaint must be dismissed where the alleged motive is less compelling than competing nonculpable explanations for defendants' behavior. *See* Mot. at 22-23.

Plaintiffs maintain that Defendants' alleged motives satisfy the scienter requirement. Opp'n at 32. However, the motives that Plaintiffs identify in the Opposition are no

different from the typical "corporate profit" motives that courts have already rejected in securities fraud cases involving pharmaceutical companies. Plaintiffs' Opposition reiterates that Defendants were motivated to deceive the market in order to "lock[] in upwards of 15 years of **patent protection**," "replac[e] Effexor and Effexor XR as they **went generic**," "**replac[e] the revenue** lost from Premarin and Prempro," "generat[e] **billions of dollars** in sales," "establish[] Pristiq as **more than a 'me too' drug**," and "enhance[] the marketing of Pristiq for **multiple indications.**" Opp'n at 32. However, courts have held that similar statements that "[a]ddress potential concerns about **patent expirations**," "make it appear that the **future of the Company** was more **promising**," and "assure the financial community of the existence of a new **blockbuster drug**" are legally insufficient to support an allegation of scienter. *See Bristol-Myers*, 312 F. Supp. 2d at 560; *Pfizer*, 538 F. Supp. 2d at 635. Here too, Plaintiffs' generic "profit" allegations are inadequate to support the scienter requirement. *See* Mot. at 24-25.

Furthermore, corporate profit is an irrational motive for disclosing only some of the adverse event data, particularly when the disclosed adverse events are more relevant to FDA approval. The Complaint identifies the Study 315 cardiac outcomes as the significant events of heart attacks and coronary occlusions and, indeed, identifies hypertension as the "most startling" of the adverse events with the most significant event rate. Compl. ¶ 25. Wyeth's disclosures are consistent with this perspective; the Company disclosed, at the ACOG conference, the treatment emergent adverse events reported by at least five percent of the subjects in any treatment group (including hypertension) as well as the cardiovascular events and explained that "no . . . causal relationship could be ascertained" between cardiovascular events and Pristiq. Mot. Aff. Ex. 11; *see also* Chepiga Decl. Ex. 5 at 70. Given the relative importance of the cardiac versus hepatic event categories and Defendants' voluntary disclosure of the cardiovascular events, the much

more compelling motive is that Defendants did not believe the hepatic events were causally related to Pristiq or that the events in Study 315 would require additional clinical trials before Pristiq could be approved for VMS.

Plaintiffs' motive allegations regarding Pristiq's "revenue generation" are also irrational in another sense. If, according to Plaintiffs, Pristiq would not be approved because of the Study 315 data and Wyeth had fully disclosed this data to the FDA, then the marketplace for the product could never be deceived by Defendants' allegedly false statements. Either the FDA would not give approval, the FDA would require restrictions on the drug's label, doctors would limit their recommendations, or patients would not seek out or take the drug; but the information was disclosed by the Company and would be reflected by the regulatory action taken or the drug's label and usage. This is not a case where Plaintiffs allege that a pharmaceutical company hid adverse safety data altogether. Accordingly, Plaintiffs' alleged motives for concealment of the data are irrational and considerably less compelling than the competing nonculpable explanations for Defendants' behavior.

Defendants also showed that it would have been illogical for Wyeth to continue to invest in Studies 319 and 321 if they had known the Study 315 safety data would prevent FDA approval. *See* Mot. at 23-24. Plaintiffs respond that "it is certainly plausible, if not more likely, that Defendants would try to stack the deck with new trials that excluded patients with cardiac or hepatic risk factors." Opp'n at 31. But Wyeth set the exclusion criteria for Studies 319 and 321 *before* Defendants learned of the Study 315 data. *See* Mot. at 7 n. 5. Thus, these studies could not have been planned to mask the Study 315 results, and Plaintiffs' argument fails.

Plaintiffs argue that it would have been advantageous for Defendants to "delay[] the bad news for a year or two." Opp'n at 31. In so doing, Plaintiffs ignore the ways in which

Defendants would have been acting *against their own economic self-interest* had they submitted the Pristiq NDA to the FDA knowing that it would not receive approval. As explained in the opening brief, because Defendants hold large amounts of stock in a Restricted Stock Trust and received a substantial number of stock options in April 2007, they had strong incentives to maximize the long-term, rather than short-term, price of Wyeth stock. *See* Mot. at 23-24. Plaintiffs' alleged motives are inconsistent, are not as cogent as the inferences favorable to Defendants to be drawn from the facts, and do not survive a *Tellabs* inquiry.

2. Defendants' Stock Sales Were Not Suspicious or Unusual

As Defendants have shown, Defendants' Class Period stock sales were not suspicious or unusual, and thus do not give rise to a strong inference of scienter. *See* Mot. at 26-32. Plaintiffs' arguments to the contrary are unavailing for a multitude of reasons.

Timing: Plaintiffs contend that the stock sales give rise to an inference of scienter because "they were highly coordinated with nearly 60% of the sales occurring in October 2006, shortly following Wyeth's October 5, 2006 annual investor conference." Opp'n at 33. Plaintiffs ignore the relevant facts, alleged in the Complaint, that belie this argument. The October sales occurred after Defendants had allegedly been issuing false and misleading statements for **over three months**. *See* Mot. at 28. Thus unlike in *Scholastic*, which Plaintiffs cite, the allegedly fraudulent statements were not "quickly" followed by Defendants' stock sales. *See* Opp'n at 33 n.18. Moreover, Defendants' sales were made **nine months** before the Company issued the press release announcing the FDA approvable letter, and just after the end of a blackout period. *See* Mot. at 28-29. As *In re KeySpan Corp. Securities Litigation* held, there is no inference of fraud where the Complaint does not explain why the sales took place well after the start of the allegedly fraudulent statements and months before any negative public disclosure. *See* 383 F.

Supp.358, 385 (E.D.N.Y. 2003). The timing is insufficient, as a matter of law, to create a strong inference of scienter.[10] *See* Mot. at 28-29.

Percentage of Stock Sold: Plaintiffs accuse Defendants of "improper[ly] challenging the allegations of percentages of stock sold." Opp'n at 34 n.20. Plaintiffs view their own computations as legitimate simply because they are based on "the Defendants' own relevant SEC Form 4s." *Id.* However, Defendants' Motion did not assert that Plaintiffs used an inappropriate source of data. Rather, Defendants challenged Plaintiffs' *methodology* of the calculations, and Plaintiffs do not respond to this challenge in any way. The law requires the inclusion of vested stock options as part of an individual's total stock holdings when calculating the percentage of stock sold. *See* Mot. at 30. Plaintiffs' calculations were improper because they excluded vested stock options. When vested stock options are accurately incorporated, it becomes clear that the percentages of stock sold by the Defendants are not large enough to support an inference of fraud. *See* Mot. at 30 (setting forth case law supporting Defendants' position that their sales of 4% to 27% of their total respective holdings do not raise an inference of guilty conduct).[11]

Number of Non-Selling Directors: Plaintiffs also argue that "[t]he fact that some other non-defendant Company directors did not sell stock during the Class Period does not negate a strong inference of scienter." Opp'n at 35. Plaintiffs misunderstand *KeySpan*, which states:

> [E]ight other KeySpan officers who were required to file public records of their stock holdings—and who are not named as defendants—did not sell any stock. . . . **[T]his fact is both relevant and appropriate to consider**. . . .[T]o hold otherwise would allow a securities fraud plaintiff to "cherry-pick" defendants based solely on the fact of whether, and how much, an insider sold.

[10] Plaintiffs cite to *Chiarella v. United States* for the proposition that "an 'insider,' such as a corporate officer, who possesses material non-public information about the company, is subject to a duty to 'disclose or abstain'—i.e., either disseminate the information to the investing public before trading the company's securities or refrain from trading until the information has been publicized." Opp'n at 33 n.18. As already discussed, Defendants were not in possession of material non-public information and thus had no duty to disclose or abstain. *See supra* Section I.B.

[11] If unvested options and restricted shares are also considered, the percentages fall even further and are even more insufficient to raise an inference of scienter. *See* Mot. at 30-31.

383 F. Supp. 2d at 384 (emphasis added); *see also In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 74-75 (2d Cir. 2001) ("Factors considered in determining whether insider trading activity is unusual include . . . the number of insiders selling."). Likewise, the fact that eleven of Wyeth's twelve directors who were required to file public records of their stockholdings did not sell stock during the Class Period detracts from any possible inference of scienter. *See* Mot. at 27.

Profit: Plaintiffs incorrectly argue that "collecting *proceeds* of $83 million" is "'massive by any measure' and supports a strong inference of scienter." Opp'n at 33-34 (emphasis added). As Plaintiffs must acknowledge, courts look at "the amount of *profit* from [stock] sales" in determining whether such sales were suspicious or unusual, not the overall proceeds. *Scholastic*, 252 F.3d at 74 (emphasis added); Opp'n at 34. Defendants' class period profits were $17.84 million, not $83.2 million.[12] *See* Mot. at 27. Moreover, profits are merely one of many factors that courts must consider, and there is no dollar amount that is "suspicious per se." *Ressler v. Liz Claiborne, Inc.*, 75 F. Supp. 2d 43, 59 (E.D.N.Y. 1999); *In re BISYS Sec. Litig.*, 397 F. Supp. 2d 430, 444 (S.D.N.Y. 2005) ("There is no *per se* rule . . . that sale of a particular monetary amount . . . is unusual."). Where, as here, the full consideration of factors indicates that stock sales were not suspicious or unusual, the complaint must be dismissed.[13]

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[12] Plaintiffs' recitation of the individual proceeds of Messrs. Essner, Martin, Mahady, and Poussot and Dr. Ruffolo as $9.23 million, $35.61 million, $10.34 million, $13.88 million, and $14.76 million, respectively, is similarly misleading. S*ee* Opp'n at 34. Sale *profits* is the correct standard because it subtracts the price paid for the shares. Defendants' *profits* are $2.80 million, $5.74 million, $2.12 million, $3.01 million, and $4.18 million, respectively.

[13] Plaintiffs argue that large profits are sufficient, on their own, to raise an inference of scienter. But each case cited by Plaintiffs considered additional factors. *See In re Oxford Health Plans, Inc. Sec. Litig.*, 187 F.R.D. 133, 139-40 (S.D.N.Y. 1999) (sales suspicious due to timing, percentage of total holdings, and profit); *In re MTC Elec. Tech. S'holders Litig.*, 898 F.Supp. 974, 980 n.4 (E.D.N.Y. 1999) (sales suspicious due to timing, conflict of interest, and profit); *Rubenstein v. Collins*, 20 F.3d 160, 169 (5th Cir. 1994) (sales suspicious due to timing and profit); *In re Suprema Specialities, Inc. Sec. Litig.*, 438 F.3d 256, 277 (3d Cir. 2006) (sales suspicious due to timing, percentage of total holdings, divergence from past stock trading patterns, and profit); *Helwig v. Vencor, Inc.*, 251 F.3d 540, 558 (6th Cir. 2001) (sales suspicious due to timing, analysis by financial media, and profit); *In re U.S. Interactive, Inc. Sec. Litig.*, No. 01-CV-522, 2002 U.S. Dist. LEXIS 16009, at *58-59 (E.D. Pa. Aug. 23, 2002) (sales suspicious due to timing, profit, and because it was first time defendants sold stock); *In re Quintel Entm't Inc. Sec. Litig.*, 72 F.Supp.2d 283, 296-97 (S.D.N.Y. 1999) (sales suspicious due to number of corporate insiders making sales, volume

Mr. Martin's Stock Sales: Plaintiffs argue that the fact of Mr. Martin's resignation in April 2007 is improper to consider on a motion to dismiss and does not account for all of his sales. Opp'n at 34 n.21. Plaintiffs ignore two cases in the opening brief—*In re Health Management Systems Securities Litigation* and *In re LaBranche Securities Litigation*— in which courts **granted motions to dismiss** because, *inter alia*, defendants' stock sales were deemed not suspicious on account of their resignations. *See* Mot. at 31-32. Second, Mr. Martin's October 2006 sale constitutes only 109,564 (17%) of the 637,641 shares he sold during the Class Period and are not suspicious for the same reasons discussed above. *See* Compl. ¶ 127. The 528,077 shares he sold in April and May 2007 account for most of the sales. *See id.* These sales are explained by his resignation and thus do not give rise to an inference of scienter. Mot. at 31.

B. Plaintiffs Have Not Alleged Conscious Misbehavior or Recklessness

Plaintiffs state that "[w]here defendants do not deny their knowledge of undisclosed facts, and those facts are properly alleged to be material, the PSLRA's strong inference of scienter has been met." Opp'n at 29. This assertion does not accurately reflect the very high standard for the "conscious misbehavior or recklessness" prong of scienter. To meet that standard, Plaintiffs would have to allege "highly unreasonable" conduct "representing an extreme departure from the standards of ordinary care…to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *Rothman v. Gregor*, 220 F.3d 81, 90 (2d Cir. 2000); *see* Mot. at 32. Mere "knowledge of undisclosed facts," as Plaintiffs themselves phrase it, does not represent such unreasonable behavior.

First, as already discussed, Plaintiffs do not allege (because they cannot) that Defendants knew during the class period that the FDA would not issue an approval letter for

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of sales, and profit); *Schlagel v. Learning Tree Int'l*, No. CV 98-6384 ABC(Ex), 1998 U.S. Dist. LEXIS 20306, at *50 (C.D. Cal. Dec. 23, 1998) (sales suspicious due to timing, unusual trading pattern, and profits).

Pristiq in July 2007. *See supra* Subsection I.A.3. The long list of pharmaceutical cases granting motions to dismiss under similar circumstances demonstrates that a drug company's failure to accurately predict FDA action does not constitute recklessness. *See* Mot. at 32-33. Plaintiffs have thus failed to plead scienter with regard to Defendants' alleged misstatements.

Second, as discussed *supra*, Plaintiffs fail to show that the alleged omissions were material or that Plaintiffs ever believed they were material. *See supra* Section I.B. As the Second Circuit explained in *Carter-Wallace II*, "awareness of adverse reports while touting [a drug's] safety does not, on its own, constitute 'strong circumstantial evidence of conscious misbehavior or recklessness. . . . Before [a causal] link [is] made . . . any inference of scienter is negated.'" 220 F.3d at 41; *see also Biogen*, 2008 WL 3115355, at *12 (plaintiffs did not plead scienter where defendants did not know at the time of causal link between drug and infections). When the court considers the entire picture of facts properly before it on this motion, it is apparent that Plaintiffs do not allege "conscious misbehavior or recklessness."[14]

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court dismiss the Complaint in its entirety, with prejudice, and without leave to replead.

Dated: New York, New York
August 25, 2008

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[14] For all of the above-stated reasons, Plaintiffs have not alleged a primary violation of the securities laws or that the Defendants "culpably participated" in any fraud, and thus their Section 20(a) claim should also be dismissed with prejudice. *See* Mot. at 35-36.